Summary of Safety and Effectiveness
Liquichek™ Cardiac Markers Control LT

1.0 Submitter

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Contact Person

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Date of Summary Preparation

May 8, 2002

2.0 Device Identification

Product Trade Name:	Liquichek™ Cardiac Markers Control LT
Common Name:	Enzyme Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	75JJT
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Bio-Rad Laboratories
Irvine, California

Liquichek™ Cardiac Markers Control LT
Docket Number: K012656

Liquichek™ Cardiac Markers
Docket Number: K961828

4.0 Description of Device

Liquichek™ Cardiac Markers Control LT is prepared from human serum with added constituents of human and animal origin, preservatives and stabilizers. The control is provided in liquid form for convenience.

5.0 Statement of Intended Use

Liquichek™ Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory procedures listed in the package insert.

6.0 Preservatives:

The Liquichek™ Cardiac Markers Control LT does not contain sodium azide as a preservative. It contains a broad-spectrum anti-microbial cocktail as a preservative where the concentration of any one ingredient is less than 0.1%. At this low level, these ingredients are not expected to cause a health hazard to the user. And thus, domestic and international regulations do not require this type of information on the vial or box label.

7.0 Comparison of the new device with the Predicate Device

Liquichek™ Cardiac Markers Control LT claims substantial equivalence to the Liquichek™ Cardiac Markers Control LT and Liquichek™ Cardiac Markers Control currently in commercial distribution.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio Rad Liquichek™ Cardiac Markers Control LT (New Device)	Bio Rad Liquichek™ Cardiac Markers Control LT (Predicate Device K012656)	Bio Rad Liquichek™ Cardiac Markers Control (Predicate Device K961828)
Similarities			
Intended Use	Liquichek™ Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.	Liquichek™ Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of an individual laboratory's specific cardiac marker procedures.	Liquichek Cardiac Markers Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.
Form	Liquid	Liquid	Liquid
Matrix	Human serum based	Human serum based	Human serum based
Differences			
Storage (Unopened)	–20°C or colder Until expiration date	–20°C or colder Until expiration date	-10 °C to –20°C Until expiration date
Open Vial Claim **At 2-8°C**	Troponin-I, Troponin T and Homocysteine: 10 days Myoglobin, CK-MB, and Digitoxin: 20 days	Troponin-I and Homocysteine 10 days Myoglobin, CK-MB, and Digitoxin 20 days	Myoglobin, Troponin I, Troponin T 10 days CK, Total, CK-MB, LD-1 Isoenzyme 20 days
Analytes	Contains: Troponin-I, Troponin T, Myoglobin, CK-MB, Homocysteine and Digitoxin	Contains: Troponin-I, Myoglobin, CK-MB, Homocysteine and Digitoxin No claim is made for expected values or stability of Troponin T.	Contains CK, Total, CK-MB, LD-1 Isoenzyme, Myoglobin, Troponin I and Troponin T.

8.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Cardiac Markers Control LT. Product claims are as follows:

8.1 Open vial: Once the control material is thawed and opened, all analytes will be stable for 20 days when stored tightly capped at 2-8°C, with the following exceptions: Troponin I, Troponin T and Homocysteine will be stable for 10 days.

8.2 Do not refreeze the control once it has been thawed.

8.3 Shelf Life: Two years when stored at –20 °C or colder

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 4 2002

Ms. Elizabeth Platt
Regulatory Affairs/Quality Assurance Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618

Re: k021498
Trade/Device Name: Liquichek™ Cardiac Markers Control LT
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Code: JJT
Dated: May 8, 2002
Received: May 9, 2002

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K021498

Device Name: **Liquichek™ Cardiac Markers Control LT**

Indications for Use:

Liquichek Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use_____

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021498